IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
Attorney Docket No. 011738.00046

In re U.S. Patent Application of Hartlaub, et al.	)	
	)	Group Art Unit: 3686
Application No. 10/002,669	)	
	)	Examiner: Najarian, Lena
Filed: October 31, 2001	)	
	)	Confirmation No. 5026
For: Patient Scheduling Techniques For An Implantable Medical Device	)	

REPLY BRIEF

Mail Stop: Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

This Reply Brief is being filed in support of Applicants' January 12, 2009 Notice of Appeal and Brief on Appeal filed March 24, 2009, and is responsive to the Examiner's Answer mailed June 3, 2009. If any fees are required or if an overpayment is made, the Commissioner is authorized to debit or credit our Deposit Account No. 19-0733, accordingly.

Page

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I. REAL PARTY IN INTEREST

The owner of this application, and the real party in interest, is Medtronic, Inc.

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II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

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III. STATUS OF CLAIMS

Claims 12-26 and 39-48 remain in the application. Claims 1-11 and 27-38 were previously withdrawn from consideration. All of the pending claims (12-26 and 39-48) stand rejected. Applicants are appealing all pending claims (12-26, and 39-48). All claims are shown in the attached Appendix at page A-1.

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IV. STATUS OF AMENDMENTS

There are no amendments subsequent to the Final Office Action dated October 10, 2008.

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V. SUMMARY OF CLAIMED SUBJECT MATTER

In making reference herein to various portions of the specification and drawings in order to explain the claimed invention (as required by 37 CFR §41.37(c)(1)(v)), Applicants do not intend to limit the claims. All references to the specification and drawings are illustrative unless otherwise explicitly stated.

Aspects of the claimed subject matter relate to implantable medical devices. Specifically, aspects of the claimed subject matter relate "to implantable drug delivery devices such as implantable drug delivery devices, and more particularly relates to ***automated patient scheduling systems and methods for implantable drug delivery devices***." (Paragraph 4, lines 1-3, emphasis added). There are two (2) pending independent claims (claims 12 and 21).

Independent claim 12 is directed to an "implantable drug delivery device for delivering at least one drug to a patient." The device comprises four elements. The first element is "at least one reservoir each containing at least one drug." As shown in an exemplary embodiment of Figure 7, the drug delivery device includes a "therapeutic substance reservoir 1244." (Paragraph 45, lines 5-6).

The second element is "a drug scheduling element for determining whether the drug should be replinished." Figure 10 is a schematic block diagram of an exemplary drug scheduling module ***of the implantable drug pump*** in accordance with one embodiment of the present invention. (Paragraph 30, lines 1-2). Figure 1 is a schematic block diagram of an overall system for drug scheduling management of an implantable drug delivery device in accordance with one embodiment of the present invention, which includes "a drug scheduling module 115 in accordance with a preferred embodiment of the present invention." (Paragraph 33, lines 1-6). In the illustrated embodiment in Figure 10, the "external device 110 generally includes a telemetry

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module 705 and a memory 710 for storing various software applications and modules for use with the present invention," and "[s]tored within the external device 110 is the drug scheduling module 115." (Paragraph 50, lines 1-3). "The drug scheduling module 115 gathers data regarding the implantable device 105 to determine whether the drug level in the implantable device 105 is low and thereby needs to be replenished." (Paragraph 50, lines 3-5). "The drug scheduling module 115 may also gather diagnostic data regarding the implantable device 105 to determine whether the device requires servicing. (Paragraph 50, lines 5-7). "As shown in the block diagram of FIGURE 10, the data regarding the implantable device 105 that the drug scheduling module 115 uses to make its determination include, for example, drug usage information 805 from the drug monitor module 735, drug management instructions 810, and pump manufacturer requirements 820." (Paragraph 50, lines 7-11). "The drug scheduling module 115 also receives drug management data 815 to determine drug order information." (Paragraph 51, lines 1-2). "[T]he drug scheduling module 115 includes a drug management algorithm 825 that serves to forecast when the next refill of the pump reservoir is required." (Paragraph 52, lines 1-2).

The third element of independent claim 12 recites an appointment scheduling module. As claimed, the appointment scheduling module is "automatically initiated by the drug scheduling module and ***without scheduling input contemporaneously provided by the patient***, for automatically scheduling an appointment to replenish the drug in the device." (Emphasis added). In an exemplary embodiment, "[a]ppointment scheduling module 830 has a scheduling management algorithm 832, which performs the function of arranging an appointment for the patient to refill the pump." (Paragraph 53, lines 1-2). An exemplary appointment scheduling module 830 is shown in Figure 10.

The fourth element of claim 12 recites "a telemetry module providing bi-directional communications with an external device for allowing the appointment scheduling module to schedule the appointment." *See* claim 12. "Referring to the schematic block diagram of FIGURE 9, the implantable device 105 includes various electrical and software components including a microprocessor 730, a flow control module 740 for controlling the flow of drug from the reservoir to the infusion port, a telemetry module 720 for providing bi-directional communication between the implantable device 105 and the external device 110, a memory 725 for storing the various software modules for use with the present invention, a drug monitor module 735, and (optionally) a drug scheduling module 115." (Paragraph 49, lines 1-7 emphasis added).

Independent claim 21 is directed to "an implantable drug delivery device having a patient scheduling feature." The device comprises eight (8) elements. The first element is "a housing." As shown in Figure 7, the "implantable drug delivery device 105 generally comprises a housing 1141." (Paragraph 45, lines 2-5).

The second element of claim 21 is "a drug reservoir carried in the housing configured to contain a therapeutic substance." Figure 7 shows an exemplary "therapeutic substance reservoir 1244." (Paragraph 45, lines 2-6).

The third element of claim 21 is "a flow control coupled to the drug reservoir for controlling the flow of the therapeutic substance from the drug reservoir through an infusion port." Figure 7 shows that "[t]he therapeutic substance pump 1246 is carried in the housing 1141" and that "[t]he therapeutic substance pump 1246 is fluidly coupled to the therapeutic substance reservoir 1244 and electrically coupled to the power source 1242." (Paragraph 46, line 1, and lines 4-6). In an exemplary embodiment, "[t]he therapeutic substance pump 1246 is a

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pump that is sufficient for infusing therapeutic substance such as a piston pump, a peristaltic pump that can be found in the SynchroMed® Infusion System available from Medtronic, Inc., or a pump powered by a stepper motor, an AC motor, a DC motor, an electrostatic diaphragm, a piezoelectric diaphragm, a piezoelectric motor, a solenoid, a shape memory alloy, and the like." (Paragraph 46, lines 6-11).

The fourth element of claim 21 recites "electronics coupled to the flow control and a power source." Figure 7 shows exemplary "electronics 1248." (Paragraph 45, lines 2-6). As shown in Figure 7, "[t]he electronics 1248 are carried in the housing 1141 and coupled to the therapeutic substance pump 1246 and the power source 1242." (Paragraph 47, lines 1-2). "The electronics 1248 include a processor 1405, memory 1410, an infusion program in memory, and transceiver circuitry 1415." (Paragraph 47, lines 2-3). "The processor 1405 can be an Application Specific Integrated Circuit (ASIC) state machine, a gate array, controller, and the like." (Paragraph 47, lines 3-5).

The fifth element of claim 21 is "a telemetry module coupled to the electronics." Referring to the exemplary schematic block diagram of Figure 9, "the implantable device 105 includes various electrical and software components including a microprocessor 730, a flow control module 740 for controlling the flow of drug from the reservoir to the infusion port, a telemetry module 720 for providing bi-directional communication between the implantable device 105 and the external device 110, a memory 725 for storing the various software modules for use with the present invention, a drug monitor module 735, and (optionally) a drug scheduling module 115." (Paragraph 49, lines 1-7 emphasis added).

The sixth element of claim 21 is "memory coupled to the electronics, the memory containing pump scheduling criteria and other scheduling criteria." As shown in Figure 7, "[t]he

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electronics 1248 are carried in the housing 1141 and coupled to the therapeutic substance pump 1246 and the power source 1242." (Paragraph 47, lines 1-2). "The electronics 1248 include a processor 1405, memory 1410, an infusion program in memory, and transceiver circuitry 1415." (Paragraph 47, lines 2-3, emphasis added). See also memory 1410 shown in the schematic block diagram of Figure 8. See also the block diagram of Figure 9, which shows "a memory 725 for storing the various software modules for use with the present invention." (Paragraph 49, lines 5-6).

The seventh element of claim 21 is "a monitoring module coupled to the memory and the electronics that monitors at least one pump operation variable." The block diagram of Figure 9 illustrates "a drug monitor module 735", wherein "[t]he drug monitor module 735 provides one or more drug usage parameters that determine the amount of drug remaining in the implantable device 105", and wherein "[d]rug usage parameters monitored by the drug monitor module 735 may include, for example and without limitation, the quantity drug consumed by the patient, the rate in which the drug is being consumed by the patient, and the estimated date that the drug in the pump will be exhausted based on the previous two parameters." (Paragraph 49, lines 6-12).

The eighth element of claim 21 is "a scheduling module coupled to the memory and the electronics, the scheduling module configured to calculate at least one relationship among the pump scheduling criteria and monitored pump variables, the scheduling module configured to decide automatically and without scheduling input contemporaneously provided by the patient whether an appointment is required, and the ***scheduling module configured to activate the telemetry module to schedule an appointment***, wherein the scheduling module is adapted to contact via the telemetry module at least one entity for the appointment scheduling automatically, and ***without scheduling input contemporaneously provided by the patient***,

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wherein the at least one entity is selected from the group consisting of a pharmacy, a caregiver, a physician, and a hospital." Figure 10 is a schematic block diagram of the drug scheduling module of the implantable drug pump in accordance with a preferred embodiment of the present invention. (Paragraph 30, lines 1-2). Figure 1 is a schematic block diagram of an overall system for drug scheduling management of an implantable drug delivery device in accordance with a preferred embodiment of the present invention, which includes "a drug scheduling module 115 in accordance with a preferred embodiment of the present invention." (Paragraph 33, lines 1-6). In the illustrated embodiment in Figure 10, the "external device 110 generally includes a telemetry module 705 and a memory 710 for storing various software applications and modules for use with the present invention," and "[s]tored within the external device 110 is the drug scheduling module 115." (Paragraph 50, lines 1-3). "The drug scheduling module 115 gathers data regarding the implantable device 105 to determine whether the drug level in the implantable device 105 is low and thereby needs to be replenished." (Paragraph 50, lines 3-5). "The drug scheduling module 115 may also gather diagnostic data regarding the implantable device 105 to determine whether the device requires servicing. (Paragraph 50, lines 5-7). "As shown in the block diagram of FIGURE 10, the data regarding the implantable device 105 that the drug scheduling module 115 uses to make its determination include, for example, drug usage information 805 from the drug monitor module 735, drug management instructions 810, and pump manufacturer requirements 820." (Paragraph 50, lines 7-11). "The drug scheduling module 115 also receives drug management data 815 to determine drug order information." (Paragraph 51, lines 1-2). "[T]he drug scheduling module 115 includes a drug management algorithm 825 that serves to forecast when the next refill of the pump reservoir is required." (Paragraph 52, lines 1-2).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

- Whether claims 12-15, 17-26, 39 and 44 are unpatentable under 35 USC § 103(a) as being obvious over the Lebel reference (U.S. Publ. No. US 2002/0016568 A1) in view of the Pilarczyk reference (U.S. Patent No. 4,766,542).
- Whether claims 40-41 and 45-46 are unpatentable under 35 USC § 103(a) as being obvious over the Lebel reference, the Pilarczyk reference and the Mayer reference (U.S. Publication No. US 2002/0010597 A1).
- Whether claim 16 is unpatentable under 35 USC § 103(a) as being obvious over the Lebel reference, the Pilarczyk reference and the Akers reference (U.S. Patent No. 6,112,182).
- Whether claims 42-43 and 47-48 are unpatentable under 35 USC § 103(a) as being obvious over the Lebel reference, the Pilarczyk reference, and the Cummings, Jr. reference (U.S. Patent No. 6,345,260).

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VII. ARGUMENTS

A. Rejection under 35 USC §103(a)

Claims 12-15, 17-26, 39 and 44

The Office Action dated October 10, 2008, alleged claims 12-15, 17-26, 39 and 44 are unpatentable under 35 USC §103(a) as being obvious over Lebel, et al., U.S. Publication No. 2002/0016568 A1 ("Lebel"), in view of Pilarczyk U.S. Patent No. 4,766,542 ("Pilarczyk"). The rejected claims include independent claims 12 and 21. Independent claim 12 substantively recites:

> An implantable drug delivery device for delivering at least one drug to a patient comprising in combination:
> (a) at least one reservoir each containing at least one drug;
> (b) a drug scheduling module for determining whether the drug should be replenished;
> (c) an appointment scheduling module automatically initiated by the drug scheduling module and without scheduling input contemporaneously provided by the patient, for automatically scheduling an appointment to replenish the drug in the device; and
> (d) a telemetry module providing bi-directional communications with an external device for allowing the appointment scheduling module to schedule the appointment,
> wherein the drug scheduling module receives data about the implantable drug delivery device, wherein the data is selected from the group consisting of drug usage information and drug management data.

(Emphasis added).

Independent claim 21 substantively recites the following:

> An implantable drug delivery device having a patient scheduling feature, comprising:
> (a) a housing;
> (b) a drug reservoir carried in the housing configured to contain a therapeutic substance;
> (c) a flow control coupled to the drug reservoir for controlling the flow of the therapeutic substance from the drug reservoir through an infusion port;
> (d) electronics coupled to the flow control and a power source;
> (e) a telemetry module coupled to the electronics;
> (f) memory coupled to the electronics, the memory containing pump scheduling criteria and other scheduling criteria;

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(g) a monitoring module coupled to the memory and the electronics that monitors at least one pump operation variable; and,

(h) a scheduling module coupled to the memory and the electronics, the scheduling module configured to calculate at least one relationship among the pump scheduling criteria and monitored pump variables, the scheduling module configured to decide automatically and without scheduling input contemporaneously provided by the patient whether an appointment is required, and the scheduling module configured to activate the telemetry module to schedule an appointment, wherein the scheduling module is adapted to contact via the telemetry module at least one entity for the appointment scheduling automatically, and without scheduling input contemporaneously provided by the patient, wherein the at least one entity is selected from the group consisting of a pharmacy, a caregiver, a physician, and a hospital.

Referring to claim 12, the Office Action of 10/10/08 recognized that Lebel does not disclose "an appointment scheduling module automatically initiated by the drug scheduling module, and without scheduling input contemporaneously provided by the patient, for automatically scheduling an appointment to replenish the drug in the device and allowing the appointment scheduling module to schedule the appointment." Likewise, when referring to claim 21, the Office Action recognized that Lebel does not disclose "the scheduling module configured to decide automatically and without scheduling input contemporaneously provided by the patient whether an appointment is required and to contact at least one entity for the appointment scheduling automatically, and without scheduling input contemporaneously provided by the patient."

The Office Action, however, contends that Pilarczyk discloses such features in Col. 1, line 52 through Col. 2, line 34 and Col. 6, lines 15-55. It is respectfully submitted that Pilarczyk does not teach these features and therefore does not remedy these or any other deficiencies of Lebel. Rather, the cited sections of Pilarczyk describe "a computerized system for contacting patients whose prescriptions are due to be refilled." (Col. 1, lines 52-54) Pilarczyk does not disclose or suggest an appointment scheduling module as recited in independent claim 12, but is instead directed to "a system for contacting customers of a pharmacy automatically to remind

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them that their prescriptions need to be refilled...." *See* Abstract of Pilarczyk. *See also* Abstract of Pilarczyk: "The voice synthesizer then reminds the customer that the prescription is due to be refilled if the medication was taken as prescribed." [Emphasis added] There is no automatic scheduling of an appointment taught in Pilarczyk and the reminder is based only on an ***assumption*** that the medication was taken at the rate it was prescribed. Nowhere in Pilarczyk is the word "appointment" mentioned, and nowhere does Pilarczyk disclose an "appointment scheduling module to schedule the appointment" as claimed in independent claim 12 or a "scheduling module configured to activate the telemetry module to schedule an appointment" as claimed in independent claim 21. For at least this reason, Applicants respectfully request reversal of the rejection.

The proposed combination of Lebel and Pilarczyk also does not result in a scheduling module as claimed in claims 12 and 21 or its equivalent. First, there is no teaching, disclosure, or even a suggestion of providing a module that automatically schedules an appointment, as claimed, anywhere within the disclosures of the two cited documents or any other art of record. Indeed, a drug device with an audible alarm (as provided in Lebel) and a telephonic reminder system (as provided in Pilarczyk) do not teach, disclose or suggest the subject matter of the rejected claims.

As elaborated in *KSR v. Teleflex*, 550 U.S. 398 (2007), the Graham factors set forth in *Graham et al. v. John Deere Co. of Kansas City et al.*, 383 U.S. 1 (1966) still control any determination of obviousness. Despite this, the Final Office Action and the Advisory Action are each silent in regards to the application of the Graham factors. Nonetheless, Applicants wish to address the allegations raised in the Office Action. First, Applicants respectfully submit that there would have been no reason for one of skill in the art to be motivated to provide an

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automatic scheduling module automatically initiated by a drug scheduling module, as recited in the instant claims, from the disclosures of Lebel and Pilarczyk. For instance, Lebel discloses the goal of "enhanc[ing] user interface capabilities in ambulatory medical systems and in particular for implantable infusion pump systems." Lebel states a concern for ***greater user involvement***, thus the asserted disclosures actually teach away from eliminating user interaction by employing the novel automatic appointment scheduling as recited in the rejected claims. For at least this reason, Applicants respectfully request reversal of the rejection.

Claims 40-41 and 45-46

Claims 40-41 and 45-46 were rejected under 35 USC §103(a) as being unpatentable over Lebel in view of Pilarczyk and further in view of U.S. Publication No. 2002/0010597 to Mayer et al. ("Mayer").

Applicants respectfully submit that Mayer does not remedy the deficiencies of Lebel and Pilarczyk. Mayer is directed to a set of software tools for a consumer to use for taking control of his or her own medical care. (*See* Abstract of Mayer). An appointment making tool is disclosed in paragraph 50 of Mayer: "This tool confirms, tracks and keeps appointments organized. For example, a patient needing an appointment for a physical." Mayer teaches appointment scheduling upon receiving ***a request from a patient*** for an appointment, as opposed to having a separate entity (i.e., a drug scheduling module) automatically initiating the request for an appointment. Although a pharmacist tool is disclosed in paragraph 39 of Mayer to give "an estimation of compliance and can prompt for refills to improve compliance," this is drastically different than the claimed subject matter and there is no further disclosure with respect to prompting for refills, such as how the pharmacist tool could actually provide a prompt. In this regard, the Office Action and the Advisory Action are again silent in regards to the

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application of the *Graham* factors. Applicants respectfully submit that there would have been no reason for one of ordinary skill in the art to remove the patient from involvement with the appointment making tool as disclosed in paragraph 50 of Mayer and configure the pharmacist tool as disclosed in paragraph 39 of Mayer to initiate the separate appointment making tool *sans* patient involvement. For at least this reason, Applicants respectfully request reversal of the rejection.

Claim 16

Claim 16 was rejected under 35 USC §103(a) as being unpatentable over Lebel in view of Pilarczyk and further in view of U.S. Patent No. 6,112,182 to Akers et al. ("Akers"). Akers is directed to a data processing system for use in managing healthcare and is unrelated to appointment scheduling, thus also does not remedy the deficiencies of the cited art. For example, Akers does not teach, either individually or in combination, at least eliminating user interaction by employing automatic appointment scheduling as recited in the rejected claims. For at least this reason, Applicants respectfully request reversal of the rejection.

Claims 42-43 and 47-48

Claims 42-43 and 47-48 were rejected under 35 USC §103(a) as being unpatentable over Lebel in view of Pilarczyk and further in view of U.S. Patent No. 6,345,261 to Cummings, Jr. et al. ("Cummings, Jr."). Cummings, Jr. is directed to an appointment scheduling interface for booking appointments with professionals. (*See* Col. 1, lines 13-16 of Cummings, Jr.) Cummings, Jr. does not remedy the deficiencies of Lebel and Pilarczyk with respect to either claim 12 or claim 21. Cummings, Jr. discloses a "[c]all center, to which clients can call through conventional telephone lines. (Col. 6, lines 46-47) "While client 10b is on the line, call center 11 can log onto the Web from any Web browser. With proper security clearance and verification,

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server 15 permits access to online master schedule database 16, which contains and displays the appointment times and dates for all physicians on the system..." (Col. 8, lines 1-7) Appointment scheduling is therefore disclosed by Cummings, Jr. to be initiated by a ***client call*** to a call center. Therefore, Cummings Jr., either individually or in combination with any other art of record, does not teach at least eliminating user interaction by employing automatic appointment scheduling as recited in the rejected claims. For at least this reason, Applicant respectfully requests reversal of the rejection.

The Applicant addresses below the arguments in the Examiner's Answer mailed June 3, 2009, in the sequence they appear in the Examiner's Answer.

Argument A

In response to Appellant's first argument, the Examiner argues that Pilarczyk discloses calculating a refill due date based on the prescription activity and storing records in a schedule file based on the calculated refill due date (citing col. 6, lines 46-55 and col. 8, lines 35-50 of Pilarczky). The Examiner's Answer raises a new argument by interpreting a "due date" to be a form of "appointment." Based on this new argument, the Examiner then argues that "[a]s such, the broadest reasonable interpretation of an appointment scheduling module would include the automatic determination of when to replenish/refill a drug, which is disclosed in Pilarczyk."

Appellant's Response to the Examiner's Argument A

The Examiner's arguments ignore the features of the claimed invention, which includes

(b) a drug scheduling module for determining whether the drug should be replenished; and

(c) an appointment scheduling module automatically initiated by the drug scheduling module

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and without scheduling input contemporaneously provided by the patient, for automatically scheduling an appointment to replenish the drug in the device. Thus, as claimed, there is a drug scheduling module that is distinct from the appointment scheduling module. The drug scheduling module determines whether the drug should be replenished, and the appointment scheduling module is "automatically initiated by the drug scheduling module and without scheduling input contemporaneously provided by the patient, for automatically scheduling an appointment to replenish the drug in the device."

Pilarcyzk does not disclose the appointment scheduling module as claimed in the pending claims. A calculated refill date in Pilarcyzk does not equate to "automatically scheduling an appointment to replenish the drug in the device." Indeed, Pilarcyzk discloses that after a calculated refill date is made, a telephone communication task is then to be undertaken. Pilarcyzk at col. 7, lines 28-29. The "schedule file" in Pilarcyzk schedules automatic telephone calling to patients, i.e., a telephone communication task wherein a telephone message "reminder" is provided to a patient that a prescription is due for a refill if it has been taken as prescribed, and that if the patient wishes to refill the prescription they need to contact the pharmacy:

> The system's software consults the first entry in the schedule file to be called and determines the phone number to be dialed, block 70. The automatic dialer then initiates the call, block 72, and begins, without waiting for the phone to be answered, to announce itself. Thus it may say "This is your pharmacy calling; if you have answered the phone, please press 2", as indicated at block 74. If no response is received within 30 seconds, the system proceeds to block 80, makes a record of the failure to reach the customer and returns to the telephone communication task, block 64, which consults the edited schedule file at block 62 for the next scheduled call.
>
> If the customer responds by pressing 2, as requested by the automatic dialing device at block 74, the software proceeds to block 102, where the fact that the call was received is recorded. The software then refers, at block 104, to the schedule file for the refill reminder information. This information includes the patient's name, the prescription number, and the name of the drug. The automatic

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> dialer/voice synthesizer device then gives a refill message which may be along the following lines:
>
> "This is the MEDMINDER service from Jones Drug on Center Street. The prescription for Mr. Smith for Tagamet, 100 milligrams is due for refill if it has been taken as prescribed. If you wish to refill prescription number 123456 please contact the pharmacy at 123-4567."
>
> Once the refill reminder message has been given, block 106, the system asks for a further response from the message receiver as shown at block 108. This response, if received, confirms that the message was delivered in full. On the other hand, if this second response from the recipient is not received, the system considers that the call was not made. In either event, as indicated at blocks 118 and 114, respectively, a record is made of the event. Thereafter, the software returns to the telephone communication block 64 which consults the schedule file, block 46, for the next scheduled call.
>
> The system will proceed through the loop defined by blocks 64-118 until all customers on the selected portion of the schedule file have been contacted or until four attempts have been made to reach the customer.

Pilarcyzk, col. 9, line 29 through col. 10, line 4.

Thus, the "thing" that is scheduled in Pilarczyk is a "reminder" telephone call to a patient that their prescription is due for a refill if it has been taken as prescribed. The patient must still contact the pharmacist if they want their prescription refilled. Pilarczyk is based on the assumption that the patient has been taking their prescription as prescribed, not on actual conditions, and certainly not on actual conditions of drug dispensing by an implantable medical device as claimed in the present invention. The proposed combination of Lebel and Pilarcyzk, even if proper, would result in the implantable device of Lebel with the additional feature of Pilarcyk being simply a "reminder" telephone call to a patient that their prescription is due for a refill if it has been taken as prescribed, not on actual dispensing of the drug by the device.

Simply put, the proposed combination of Lebel and Pilarczyk does not result in an appointment scheduling module automatically initiated by the drug scheduling module and without scheduling input contemporaneously provided by the patient, for automatically

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scheduling an appointment to replenish the drug in the device. When the basic factual inquiries of *Graham v. John Deere Co.*, 383 U.S. 1 (1966) are properly made, it is clear that the pending claims would have been not been obvious to a person of ordinary skill in the art at the time of invention. The rejection of the claims should be reversed.

CONCLUSION

In sum, the pending independent claims are each patentable over the cited art. The pending dependent claims are patentable over the cited art for at least the same reasons as independent claims from which they depend and for the additional features recited therein.

Accordingly, for at least the above reasons, Applicants respectfully request reconsideration and reversal of the rejections in regards to the pending claims. The rejections contained in the Action of October 10, 2008 should be reversed for at least the reasons recited above.

Respectfully submitted,

Dated: August 3, 2009

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CLAIMS APPENDIX

1. A computing device in communication with an implantable device for delivering therapy to a patient, the implantable device having a monitor module configured to monitor at least one parameter of the implantable device, the computing device comprising in combination:

(a) a drug scheduling module for determining whether an appointment is necessary to service the implantable device based upon the parameter from the monitor module;

(b) a memory for storing therein the scheduling module and at least one scheduling preference; and

(c) a telemetry module providing bi-directional communication between the computing device and the implantable device.

2. The computing device of claim 1, wherein the drug scheduling module determines whether an appointment is necessary to perform the service selected from the group consisting of a software update, a software modification, a pump refill, and a power supply recharge.

3. The computing device of claim 1, wherein the parameter is a drug usage parameter selected from the group consisting of a quantity drug consumed, a rate in which drug is being consumed, and an estimated date that drug will be exhausted.

4. The computing device of claim 1, wherein the scheduling module receives data from the implantable device, wherein the data is selected from the group consisting of drug usage information, drug management instructions, pump manufacturer requirements, and drug management data.

5. The computing device of claim 4, wherein the drug management instructions is selected from the group consisting of order a drug delivery device refill kit, notify primary care physician of drug order, notify specialty care physician of drug order, notify drug pharmacy to order drug, notify patient's employer of drug order, deliver drug to a specified location, and bill drug to a payer.

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6. The computing device of claim 1, wherein the scheduling module receives drug management data selected from the group consisting of name of drug manufacturer, date drug was manufactured, and name of pharmacy carrying the drug.

7. The computing device of claim 1, wherein the scheduling module includes a drug management algorithm to forecast when a next refill of pump reservoir is required.

8. The computing device of claim 1, further comprising an appointment scheduling module for arranging an appointment to service the implantable device.

9. The computing device of claim 8, wherein the appointment scheduling module is capable of contacting at least one entity for the appointment, wherein the entity is selected from the group consisting of a pharmacy, a caregiver, a physician, a hospital, and the patient.

10. The computing device of claim 9, wherein the computing device is operatively coupled to the entity via a computing network.

11. The computing device of claim 10, wherein the computing network is an Internet.

12. An implantable drug delivery device for delivering at least one drug to a patient comprising in combination:

(a) at least one reservoir each containing at least one drug;

(b) a drug scheduling module for determining whether the drug should be replenished;

(c) an appointment scheduling module automatically initiated by the drug scheduling module and without scheduling input contemporaneously provided by the patient, for automatically scheduling an appointment to replenish the drug in the device; and

(d) a telemetry module providing bi-directional communications with an external device for allowing the appointment scheduling module to schedule the appointment,

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wherein the drug scheduling module receives data about the implantable drug delivery device, wherein the data is selected from the group consisting of drug usage information and drug management data.

13. The implantable drug delivery device of claim 12, wherein the appointment scheduling module contacts via the external device at least one entity for the appointment, wherein the entity is selected from the group consisting of a pharmacy, a caregiver, a physician, a hospital, and the patient.

14. The implantable drug delivery device of claim 12, the drug scheduling module further receives drug management instruction.

15. The implantable drug delivery device of claim 14, wherein the drug management instructions is selected from the group consisting of order a drug delivery device refill kit, notify primary care physician of drug order, notify specialty care physician of drug order, notify drug pharmacy to order drug, notify patient's employer of drug order, deliver drug to a specified location, and bill drug to a payer.

16. The implantable drug delivery device of claim 12, wherein the drug scheduling module receives drug management data selected from the group consisting of name of drug manufacturer, date drug was manufactured, and name of pharmacy carrying the drug.

17. The implantable drug delivery device of claim 12, wherein the drug scheduling module includes a drug management algorithm to forecast when a next refill of pump reservoir is required.

18. The implantable drug delivery device of claim 12, wherein the appointment scheduling module is capable of contacting at least one entity for the appointment, wherein the entity is selected from the group consisting of a pharmacy, a caregiver, a physician, a hospital, and the patient.

19. The implantable drug delivery device of claim 18, wherein the implantable drug delivery device is in communication with a computing device, the computing device operatively coupled to the entity via a computing network.

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20. The implantable drug delivery device of claim 19, wherein the computing network is an Internet.

21. An implantable drug delivery device having a patient scheduling feature, comprising:

(a) a housing;

(b) a drug reservoir carried in the housing configured to contain a therapeutic substance;

(c) a flow control coupled to the drug reservoir for controlling the flow of the therapeutic substance from the drug reservoir through an infusion port;

(d) electronics coupled to the flow control and a power source;

(e) a telemetry module coupled to the electronics;

(f) memory coupled to the electronics, the memory containing pump scheduling criteria and other scheduling criteria;

(g) a monitoring module coupled to the memory and the electronics that monitors at least one pump operation variable; and,

(h) a scheduling module coupled to the memory and the electronics, the scheduling module configured to calculate at least one relationship among the pump scheduling criteria and monitored pump variables, the scheduling module configured to decide automatically and without scheduling input contemporaneously provided by the patient whether an appointment is required, and the scheduling module configured to activate the telemetry module to schedule an appointment, wherein the scheduling module is adapted to contact via the telemetry module at least one entity for the appointment scheduling automatically, and without scheduling input contemporaneously provided by the patient, wherein the at least one entity is selected from the group consisting of a pharmacy, a caregiver, a physician, and a hospital.

22. The implantable drug delivery device of claim 21, wherein the scheduling module determines whether an appointment is necessary to perform a service selected from the group consisting of a software update, a software modification, a pump refill, and a power supply recharge.

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23. The implantable drug delivery device of claim 21, wherein the scheduling module communicates via the telemetry module with an external device.

24. The implantable drug delivery device of claim 21, wherein the scheduling module contacts via the telemetry module the patient for the appointment scheduling.

25. The implantable drug delivery device of claim 23, wherein the implantable drug delivery device is in communication with a computing device operatively coupled to the entity via a computing network.

26. The implantable drug delivery device of claim 25, wherein the computing network is an Internet.

27. A method for scheduling activities to support an implantable drug delivery device, comprising:

(a) establishing scheduling criteria;

(b) monitoring pump variables;

(c) calculating at least one relationship among pump scheduling criteria, other scheduling criteria and monitored pump variables;

(d) deciding whether a pump scheduling activity should be reported;

(e) reporting the pump scheduling activity from the implantable drug pump into a communications medium; and,

(f) scheduling the pump scheduling activity with a party.

28. The method of claim 27, wherein the step of deciding includes the step of determining whether an appointment is necessary to perform a service selected from the group consisting of a software update, a software modification, a pump refill, and a power supply recharge.

29. Computer executable instructions for performing the steps recited in claim 27.

30. The method of claim 27, wherein the step of monitoring pump variables includes the step of monitoring at least one drug usage parameter selected from the group consisting of a

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quantity drug consumed, a rate in which drug is being consumed, and an estimated date that drug will be exhausted.

31. The method of claim 27, wherein the step of establishing scheduling criteria includes the step of obtaining scheduling data selected from the group consisting of drug usage information, drug management instructions, pump manufacturer requirements, and drug management data.

32. The method of claim 31, wherein the drug management instructions is selected from the group consisting of order a drug delivery device refill kit, notify primary care physician of drug order, notify specialty care physician of drug order, notify drug pharmacy to order drug, notify patient's employer of drug order, deliver drug to a specified location, and bill drug to a payer.

33. The method of claim 27, wherein the step of establishing scheduling criteria includes the step of obtaining drug management data selected from the group consisting of name of drug manufacturer, date drug was manufactured, and name of pharmacy carrying the drug.

34. The method of claim 27, wherein the step of deciding whether a pump scheduling activity should be reported is performed by a drug management algorithm.

35. The method of claim 27, wherein the step of scheduling the pump scheduling activity with a party is performed by an appointment scheduling module.

36. The method of claim 27, wherein the step of scheduling the pump scheduling activity includes the step of contacting the party selected from the group consisting of a pharmacy, a caregiver, a physician, a hospital, and the patient.

37. The method of claim 36, wherein the step of contacting is performed via a computing network.

38. The method of claim 36, wherein the step of contacting is performed via an Internet.

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39. The implantable drug delivery device of claim 12, wherein the appointment scheduling module comprises a scheduling management algorithm capable of being enabled by the drug scheduling module to initiate the automatic scheduling of an appointment.

40. The implantable drug delivery device of claim 39, wherein the scheduling management algorithm receives predetermined scheduling preferences upon being enabled to initiate the automatic scheduling of an appointment.

41. The implantable drug delivery device of claim 40, wherein the predetermined preferences are selected from the group consisting of a number of days prior to pump reservoir drug depletion before the pump is refilled, date and time preferences of the pump refill technician or physician, date, time and place preferences of the patient and a caregiver, date, time and availability of clinic rooms, the proximity of a clinic to the patient and pump refill technicians, holiday and work schedules, a pharmacist's delivery timeline, and availability of back-up hospital staff.

42. The implantable drug delivery device of claim 12, wherein the appointment scheduling module records whether all entities being scheduled have acknowledged acceptance of the scheduled appointment.

43. The implantable drug delivery device of claim 12, wherein the appointment scheduling module searches for another appointment time in the event that not all entities being scheduled have acknowledged acceptance of the scheduled appointment.

44. The implantable drug delivery device of claim 21, wherein the appointment scheduling module comprises a scheduling management algorithm capable of being enabled to initiate the automatic scheduling of an appointment.

45. The implantable drug delivery device of claim 44, wherein the scheduling management algorithm receives predetermined scheduling preferences upon being enabled to initiate the automatic scheduling of an appointment.

46. The implantable drug delivery device of claim 45, wherein the predetermined preferences are selected from the group consisting of a number of days prior to pump reservoir

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drug depletion before the pump is refilled, date and time preferences of the pump refill technician or physician, date, time and place preferences of the patient and a caregiver, date, time and availability of clinic rooms, the proximity of a clinic to the patient and pump refill technicians, holiday and work schedules, a pharmacist's delivery timeline, and availability of back-up hospital staff.

47. The implantable drug delivery device of claim 21, wherein the appointment scheduling module records whether all entities being scheduled have acknowledged acceptance of the scheduled appointment.

48. The implantable drug delivery device of claim 21, wherein the appointment scheduling module searches for another appointment time in the event that not all entities being scheduled have acknowledged acceptance of the scheduled appointment.

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EVIDENCE APPENDIX

None.

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RELATED PROCEEDINGS APPENDIX

None.

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